

**REMARKS**

Reconsideration of the rejection of all claims is respectfully requested in view of the above amendments and the following remarks.

***Amendment of Title of Invention***

The Title of the Invention has been amended to correct an obvious typographical error, simply changing "OF" to "OR", so that the Title reads the same as the title of the published PCT application, of which the present application is the US National Stage.

***Claim Amendments***

Claims 1, 2 and 3 have been cancelled as being in a "use" format not generally accepted under US practice.

The substance of claim 4 has been incorporated in claim 7, and thus claim 4 has been cancelled.

Claim 7 has been placed in independent form by incorporating the substance of the method recitation from claim 4 in modified form. Thus claim 7 is now more specifically directed toward a "method of treatment" of "functional constipation or C-IBS" in a warm-blooded animal which comprises administering to said animal an effective amount of an IBAT inhibitor selected from the benzothiadiazepines recited in claim 7. As discussed further below in relation to the grounds for rejection, the last two lines of claim 7 have been amended to more specifically define the term "prodrug."

Claim 5 has been amended to be dependent on claim 7, more specifically directing the method to the treatment of functional constipation.

Claim 6 has been amended to be dependent on claim 7, more specifically directing the method to the treatment of C-IBS.

These amendments are being made for purposes of expediting the prosecution of this application to an early allowance, and are being made without waiver or prejudice to Applicants' right to prosecute any deleted subject matter in one or more continuing applications.

It should be apparent from the above description that no new matter has been added, and therefore entry of these amendments is believed to be in order and is respectfully requested. Following entry of these amendments, claims 5, 6 and 7 remain pending in this application.

***Objection to Abstract***

The abstract of the disclosure has been objected to as not being drawn to the subject matter currently under consideration. A substitute Abstract has been provided on a separate page which it is believed overcomes this objection.

***Claim Rejections - 35 USC § 112, 2nd Paragraph***

The rejection of claims 1, 3 and 4 as being indefinite has been overcome by the cancellation of these claims and the term “such as man” does not appear in the remaining claims.

The rejection of claims 1 and 4-7 as being in a “use” format has been overcome by the cancellation of claims 1-4 and the amendments to claims 5-7 which place them in a proper method form.

***Claim Rejections - 35 USC §101***

The rejection of claims 1 and 4-7 as being in a “use” format has been overcome by the cancellation of claims 1-4 and the amendments to claims 5-7 which place them in a proper method form.

***Claim Rejections - 35 USC § 112, 2nd Paragraph***

Claims 1, 2 and 4 have been rejection under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement in relation to the recitation of the term “or a prodrug thereof” with respect to an IBAT inhibitor. Applicants respectfully disagree, as the term “pro-drug” in relation to the disclosed IBAT inhibitors is specifically described in the specification at page 26, lines 7-31. Nevertheless, in order to expedite the prosecution of this application to allowance, the term “pro-drug” has been replaced in independent claim 7 by

the more specific definition thereof, being “an *in vivo* hydrolysable ester formed on an available carboxy or hydroxy or an *in vivo* hydrolysable amide formed on an available carboxy thereof.” Clear support for this recitation is found in the specification at page 26, lines 7-31, and a number of suitable esters that can be formed on available carboxy or hydroxy groups of the compounds recited in claim 7, as well as a number of suitable amides that can be formed on available carboxy groups of such compounds, are specifically listed in this portion of the specification. It is respectfully submitted that such *in vivo* hydrolysable esters and amides are clearly “described” as a part of Applicants’ invention, and persons skilled in this art would be enabled to select and make suitable such esters and amides, particularly in view of the very specific guidance in the specification as noted above. It is therefore submitted that the amendments to the claims (specifically claim 7) have overcome this ground for rejection.

Claim 4 has also been rejected on grounds that the specification does not reasonably provide enablement for the “prevention of constipation from any cause or etiologic factor.” It is respectfully submitted that this ground for rejection has been overcome by the combination of the method recitation from (now cancelled) claim 4, in modified form, with the claim 7 recitation of specific benzothiadiazepine compounds. As now amended, independent claim 7 is directed toward a “method of treatment” of “functional constipation or C-IBS” in a warm-blooded animal which comprises administering to said animal an effective amount “of an IBAT inhibitor selected from” the specific benzothiadiazepine compounds listed in claim 7.

The term “constipation” is clearly defined at specification page 4, lines 20-32 as referring to functional constipation and C-IBS. Nevertheless, in order to expedite the prosecution of this application, claim 7 now specifically recites “functional constipation or C-IBS.” The meaning of each of these terms is described in the specification, and in particular is defined according to “Rome 2 Criteria” (Gut 45 (Suppl 2): 43, 1999, II43-II47 (see specification page 4, lines 30-32).

Additionally, claim 7 is now directed toward the “treatment” of functional constipation and C-IBS. The recitation of “prophylaxis” is believed to be unnecessary inasmuch as the ordinary meaning of the term “treatment” would encompass the

administration of the claimed therapy to patients who have had indications of constipation in order to maintain regularity over a period of time.

In view of the above amendments and discussion, it is respectfully submitted that the skilled person would be fully enabled by the specification (without undue experimentation) to carry out the "treatment" of "functional constipation or C-IBS" by administration of a compound that is specifically itemized in claim 7. It is therefore respectfully submitted that independent claim 7 and dependent claims 5 and 6 are fully enabled by the specification, and withdrawal of this ground for rejection is therefore appropriate.

***Claim Rejections - 35 USC § 102(e)***

Claims 1-4 have been rejected under 35 U.S.C. 102(e) as being anticipated by Lindquist, A-M, US 2005/0124557. This ground for rejection has been obviated by the cancellation of each of claims 1-4. Moreover, it is respectfully submitted that the fact that claim 7 is directed toward the administration of the specific compounds recited therein fully distinguishes claim 7 (and thus necessarily dependent claims 5 and 6) from the Lindquist reference. Accordingly, it is respectfully requested that this ground for rejection be withdrawn.

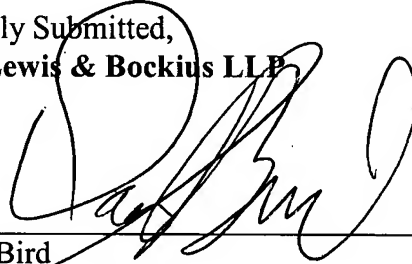
***Conclusion***

All grounds for objection and or rejection having been addressed by the above amendments and remarks and overcome, it is believed that each of presently pending claims 5-7 is now in condition for allowance, and a Notice to that effect is respectfully requested. However, if there are any questions or remaining issues that need to be resolved before allowance, it is suggested that the Examiner telephone the undersigned to see if their resolution can be expedited.

**EXCEPT** for issue fees payable under 37 C.F.R. § 1.18, the Director is hereby authorized by this paper to charge any additional fees during the entire pendency of this application including fees due under 37 C.F.R. §§ 1.16 and 1.17 which may be required, including any required extension of time fees, or credit any overpayment to Deposit

Account 50-0310. This paragraph is intended to be a **CONSTRUCTIVE PETITION FOR EXTENSION OF TIME** in accordance with 37 C.F.R. § 1.136(a)(3).

Respectfully Submitted,  
**Morgan Lewis & Bockius LLP**



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